

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK**

BAUSCH & LOMB INCORPORATED and
WYETH LLC,

Plaintiffs,
v.

DECISION & ORDER
13-CV-6498

VITAMIN HEALTH, INC.,

Defendant.

Preliminary Statement

Plaintiffs Bausch & Lomb Incorporated and Wyeth LLC (collectively "Bausch & Lomb" or "plaintiffs") bring this action under federal patent law, claiming that defendant Vitamin Health, Inc. ("Vitamin Health" or "defendant") has infringed two patents jointly owned by plaintiffs. Specifically, plaintiffs contend that defendant has infringed United States Patent Nos. 6,660,297 ("the '297 patent") and 8,603,522 ("the '522 patent"), both of which disclose a nutritional supplement intended to promote retinal health, by making and selling a vitamin supplement that utilizes, either literally or through the use of equivalent formulations, the inventions described in the patents. Plaintiffs also contend that defendant has engaged in false advertising and unfair competition in violation of the Lanham Act. In accordance with the provisions of 28 U.S.C. §

636(c), the parties have consented to the jurisdiction of this Court for all dispositive matters, including trial.

On November 13, 2014, the undersigned held a hearing pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996) ("Markman") to construe the disputed claims of the '297 and '522 patents. At the hearing and in pre- and post-hearing briefs, the parties set forth their respective positions as to how the disputed claims should be construed and, on January 15, 2015, the Court issued a thirty-seven page Decision & Order construing the terms in the patents' claims. Docket # 130. However, on June 16, 2016, the Court received letters from both parties requesting a supplemental claim construction following a dispute that arose during expert discovery and pre-trial motion practice. In short, the parties have conflicting constructions of the term "early age-related macular degeneration" as used in the '522 patent and, in order to prevent them from improperly arguing conflicting claim constructions of the term to the jury, the Court needs to construe the term. The following represents my conclusion of law with respect to the interpretation of the disputed claim of the '522 patent.

Factual Background

Familiarity with the facts of this case, as set forth more fully in the Court's previous Markman decision, is presumed.

See Docket # 130. With the instant claim construction, the Court is concerned with the '522 patent and, in particular, its claims that the patented formula treats individuals with "early age-related macular degeneration." See Docket # 310; see also Docket # 311. According to the '522 patent specification, the invention is "[a] safe and effective method of preventing, stabilizing, reversing and/or treating macular degeneration or visual acuity loss by reducing the risk of developing late stage or advanced age-related macular degeneration in persons with early age-related macular degeneration" Moreover, the preambles in claims one through seven and eleven through twenty in the '522 patent contain terms related to treating or stabilizing "persons with early age-related macular degeneration." The parties, apparently having not realized a dispute existed as to the meaning of this term until they began conducting expert discovery, now request that the undersigned construe the disputed term.

Discussion

I. General Principles regarding Claim Construction: In Markman v. Westview Instruments, Inc., the Supreme Court held that "construction of a patent, including terms of art within its claim, is exclusively within the province of the court." 517 U.S. 370, 372 (1996); see also Teva Pharm. USA, Inc. v.

Sandoz, Inc., 574 U.S. ___, 135 S. Ct. 831, 835 (2015) (reaffirming Markman even where the construction of a term has "evidentiary underpinnings"). Because the meaning of claim terms is often "the central issue of patent litigation," and because "most aspects of trial hing[e] on this determination . . . a conscientious court will generally endeavor to make this ruling before trial." Loral Fairchild Corp. v. Victor Co. of Japan, Ltd., 911 F. Supp. 76, 79 (E.D.N.Y. 1996) (citing Markman) (quotation omitted). Indeed, it is confusing and "improper for counsel to argue conflicting claim constructions to the jury." ART+COM Innovationpool GmbH v. Google Inc., No. 1:14-217-TBD, 2016 WL 2945194, at *1 (D. Del. May 20, 2016) (citing Cytologix Corp. v. Ventana Med. Sys., Inc., 424 F.3d 1168, 1172 (Fed. Cir. 2005)). Thus, in the pre-trial stage, the court "has considerable latitude in determining when to resolve issues of claim construction." Cytologix Corp., 424 F.3d at 1172 (citing Jack Guttman, Inc. v. Kopykake Enters., Inc., 302 F.3d 1352, 1361 (Fed. Cir. 2002)). A court may, for example, "revisit[] and alter[] its interpretation of the claim terms as its understanding of the technology evolves." Jack Guttman, Inc., 302 F.3d at 1361.

In determining how to construe claim terms, "the court should look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification, and, if

in evidence, the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) (citing Markman, 52 F.3d at 979). "Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." Id. Often, "an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term" and, in such circumstances, reliance on extrinsic evidence such as expert testimony is "improper." Id. at 1583. However, "there is no magic formula or catechism for conducting claim construction." Phillips v. AWH Corp., 415 F.3d 1303, 1324 (Fed. Cir. 2005). Courts are not obligated to consider any particular source in any particular order, so long as the sources considered "are not used to contradict claim meaning that is unambiguous in light of the intrinsic evidence." Id. (citations omitted). "The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." Profectus Tech. LLC v. Huawei Tech. Co., Ltd., ___ F.3d ___, 2016 WL 3033148, at *3 (Fed. Cir. 2016) (quoting Reinshaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998)).

Generally, courts should give claims' terms their ordinary and customary meaning, unless the patentee chooses to define them in a specific manner. Vitronics, 90 F.3d at 1582.

Ordinary and customary meaning refers to the "meaning that a 'term would have to a person of ordinary skill in the art in question at the time of the invention.'" Howmedica Osteonics Corp. v. Zimmer, Inc., ___ F.3d ___, 2016 WL 2754049 (Fed. Cir. 2016) (quoting Phillips, 415 F.3d at 1312-13). However, if the patentee chooses to be their own lexicographer, the specified definitions assigned to particular words or terms must be found either in the specification or the file history. Vitronics, 90 F.3d at 1582. Accordingly, it is necessary to review the specification to determine if any specialized meanings have been given to terms used in the patent. Id. The specification "is always highly relevant to the claim construction analysis" and is often dispositive; "it is the single best guide to the meaning of a disputed term." Phillips, 415 F.3d at 1315 (quoting Vitronics, 90 F.3d at 1582). Finally, with respect to intrinsic evidence, the prosecution history of the patent may often be of "critical significance" in defining claim terms; it frequently contains express representations made by the applicant regarding the scope of limitations of the claims and, therefore, is a valuable resource in determining the meanings of the claims' terms. Vitronics, 90 F.3d at 1582.

II. Construction of the Term "Early Age-Related Macular Degeneration": The parties dispute the meaning of the claim term "early age-related macular degeneration," which appears in the

abstract, specification, and preambles of many claims in the '522 patent. In every instance that it appears, the term is referring to the impairment for which the patented nutritional supplement is designed to treat.

Plaintiffs contend that the intrinsic and extrinsic evidence require this Court to construe the term "early age-related macular degeneration" to mean "age-related macular degeneration ('AMD') prior to advanced or late AMD, which in post-AREDS¹ terminology includes 'early/intermediate-stage' AMD (and also advanced AMD in one eye only)." Docket # 310 at 1-2. Plaintiffs assert that when the patent application was filed in March 2001, AMD was classified as either early or late stage; it was not until several months later, in October 2001, that the term intermediate AMD was first used in an AREDS-related press release and not until 2003 that an official AREDS report used the term. Id. at 7-10. Accordingly, plaintiffs argue that the term "early age-related macular degeneration" from the '522 patent is now understood to include early AMD, intermediate AMD, and advanced AMD in one eye only - the latter two being the only

¹ AREDS, which stands for the Age-Related Eye Disease Study, is a multi-year study conducted by the National Eye Institute demonstrating that the nutritional supplements disclosed in the '297 and '522 patents slow and treat vision loss from age-related macular degeneration.

stages of AMD that benefitted from the formula used in AREDS. Id. at 1-2, 8.

Vitamin Health argues that the term "early age-related macular degeneration" should be construed to mean category two AMD as defined by the AREDS study. Docket # 311 at 8. Put differently, early AMD "should not be interpreted to include 'intermediate AMD' or 'late AMD in one eye.'" Id. In support of its position, defendant relies on the AREDS report. To summarize: AREDS participants were divided into four categories based on their level of AMD-related symptomology. These categories became the basis for the contemporary classification of AMD: category one is now no AMD, category two is early AMD, category three is intermediate AMD, and category four is late or advanced AMD. The supplements used in the study, now the inventions disclosed in the patents, were not successful in treating participants in categories one and two but helped participants in category three and participants with category four AMD in one eye. Accordingly, defendant argues that the claim term "early age-related macular degeneration" in the '522 patent should be construed to mean category two AMD only. See Docket # 311 at 5-8.

A review of the evidence, however, indicates that the term "early age-related macular degeneration" should be construed to mean early AMD, intermediate AMD, and advanced AMD in one eye

only. To start, the '522 patent's specification, which "is the single best guide to the meaning" of this term, favors this construction. Phillips, 415 F.3d at 1315 (quoting Vitronics, 90 F.3d at 1582). Nothing in the '522 patent's specification indicates that the term "early age-related macular degeneration" was given a specialized definition, instructing this Court to construe the term to mean what it "would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Id. at 1313. To that end, the specification provides useful context on how the invention was intended to operate when the patent application was filed. For example, the '522 patent's specification states that the patented formula was based on the supplement used in a "National Eye Institute (NIH/ADAMHA), multicenter cohort study of 4,757 participants" on the "safe and effective prevention, stabilization, reversal and/or treatment of macular degeneration or visual acuity loss" - also referred to as AREDS. Based on the findings from AREDS, the specification further states that the patented formula is designed in part to provide "[a] safe and effective method of preventing, stabilizing, reversing and/or treating macular degeneration or visual acuity loss by reducing the risk of developing late stage or advanced age-related macular degeneration in persons with early age-related macular

degeneration" This language is then used in a number of the '522 patent's claims, which disclose "[a] method for stabilizing visual acuity loss in persons with early age-related macular degeneration" Thus, at a minimum, in failing to mention intermediate AMD, the '522 patent's specification and claim terms suggest that the term intermediate AMD likely was not contemplated by or known to the inventors at the time of the patent application's filing. More importantly, the specification provides the Court with a background to consider when determining what construction best defines the term "early age-related macular degeneration" while also aligning with the '522 patent's description of the invention - that is, a nutritional supplement designed to reduce the risk of developing advanced AMD in persons with earlier stages of AMD pursuant to AREDS. Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998) ("The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." (citations omitted)).

However, in order to fully understand what the term "early age-related macular degeneration" meant to a person of ordinary skill in the art in question at the time of the invention, the Court will also consult extrinsic evidence. See, e.g., Phillips, 415 F.3d at 1319 ("[B]ecause extrinsic evidence can

help educate the court regarding the field of the invention and can help the court determine what a person of ordinary skill in the art would understand claim terms to mean, it is permissible for the district court in its sound discretion to admit and use such evidence."). Indeed, the construction defendant urges this Court to adopt - that the term "early age-related macular degeneration" in the '522 patent should be construed to mean AREDS category two AMD, which the study found to be unresponsive to the supplement - is puzzlingly irreconcilable with the patent's description of the invention. That's because, as the extrinsic evidence reveals, the term "early age-related macular degeneration" had a different meaning at the time the patent application was filed than it does now. As plaintiffs persuasively argue, when the patent application was filed in March 2001, AMD was classified as either early or late stage. See Docket # 310 at 7-10. Plaintiffs have presented expert deposition testimony and an expert report, reports on scientific studies, and medical textbooks all indicating that there was only early and late AMD at the time of the application's filing, and that the term intermediate AMD developed as an offshoot of early AMD later. Id. Conversely, defendant has provided no extrinsic evidence to dispute plaintiffs' definition of the term at the time of the invention. Indeed, even defendant's experts

acknowledge that, at some point, there were only two categories of AMD - early and late. Id.

Thus, it is clear to the Court that the commonly understood definition of the term "early age-related macular degeneration" changed over time. Had the inventors of the '522 patent filed their patent application using the same language yesterday, the Court's outcome would undoubtedly differ. However, the Court must consider how a person of ordinary skill in the art would have understood the term when the patent application was filed. See Phillips, 415 F.3d at 1313. Moreover, the Court is required "to consider the specification as a whole, and to read all portions of the written description, if possible, in a manner that renders the patent internally consistent." Budde v. Harley-Davidson, Inc., 250 F.3d 1369, 1379-80 (Fed. Cir. 2001). Internal consistency can only be achieved when the term "early age-related macular degeneration" is construed to cover the stages of AMD that were susceptible to treatment according to the study on which the patent is based. It defies common sense and runs contrary to the intrinsic and extrinsic evidence to think that the inventors intended their patent's claims to solely encompass the only stage of AMD found to be unresponsive to their invention. Accordingly, and in order to provide a construction that comports with the claim language while still aligning with the patent's description of the invention and the

understanding of a person of ordinary skill in the art at the time the patent application was filed, I construe the term "early age-related macular degeneration" to mean early AMD, intermediate AMD, and advanced AMD in one eye only.

Conclusion

Based on the language of the '522 patent, including the claims and specifications, and in light of the extrinsic evidence provided by the parties, I construe the disputed claim term as set forth above.

SO ORDERED.

A handwritten signature in black ink, appearing to read 'Jonathan W. Feldman', is written over a horizontal line.

JONATHAN W. FELDMAN
United States Magistrate Judge

Dated: July 7, 2016
Rochester, New York